

510(K) SUMMARY

MAY 23 2003

K030230
Page 1 of 2

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1.0 Submitter's Name: AViTA Corp

Address: 9F, No. 78, Sec. 1, Kwang-Fu Rd., San-Chung, Taipei County,
Taiwan, R.O.C.

Phone: 001-886-2-85121568

Fax: 001-886-2-85121347

Contact: Mr. Geo Lin, General Manager

2.0 Device Name: AViTA BPM1Series (Wrist Type) Blood Pressure Meter (or Monitor)

Model No.: BPM1XY

- The first Character (blank , 0-9 or A-Z)is for the **minor change** revision of device (The Minor change meaning device change that do not affect the conformity test result of EMC & Safety, ie. IEC 60601-1 and IEC 60601-1-2)

- The second Character (blank , 0-9 or A-Z) is for the color of the housing

(for example **Wellex Blood Pressure Monitor # BPM101**, is for the first revision of device design and the present version of color & artwork)

3.0 Classification: Class II

4.0 Predicate Device: AViTA BPM1 Series Wrist Type Blood Pressure Monitor has similar general design with HL-168D Wrist Blood Pressure Monitor(K012310) marketed by Health & Life Co., Ltd..

5.0 Device Description: AViTA BPM1 Series Wrist Type Blood Pressure Meter is designed to measure the systolic and diastolic blood pressure, and pulse rate(heart of an individual).

6.0 Intended Use: AViTA BPM1 Series Wrist Type Blood Pressure Meter is intended to measure the systolic and diastolic blood pressure, and pulse rate(heart rate) by using an inflating cuff which is wrapped around the wrist. The Device is indicated for use by people over 15 years old in home use.

7.0 Performance
Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included EN-1060-1, EN-1060-3, ANSI/AAMI SP-10, IEC 60601-1 and IEC 60601-1-2 requirements. A comparison study with device that use auscultatory method was performed to validate the performance of the **AVITA BPM1 Series Wrist Type Blood Pressure Meter**. The comparison study demonstrated that the clinical repeatability of **AVITA BPM1 Series Wrist Type Blood Pressure Meter** is statistically and clinically acceptable.

8. Conclusions:

The **AVITA BPM1 Series Wrist Type Blood Pressure Meter** have the same intended use and similar technological characteristics as **HL-168D Wrist Blood Pressure Monitor(K012310)** marketed by **Health & Life Co., Ltd.**. Moreover, bench testing contained in this submission and clinical testing supplied demonstrate that any differences in their technological characteristics do not raise and new questions of safety or effectiveness. Thus, the **AVITA BPM1 Series Wrist Type Blood Pressure Meter** is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2003

AViTA Corporation
c/o Ms. Jennifer Reich
3892 South America West Trail
Flagstaff, AZ 86001

Re: K030230

Trade Name: AViTA BPM 1 Series (Wrist type) Blood Pressure Meter (or Monitor)

Regulation Number: 21 CFR 870.1130

Regulation Name: Non-Invasive blood measurement system

Regulatory Class: Class II (two)

Product Code: DXN

Dated: April 7, 2003

Received: April 18, 2003

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

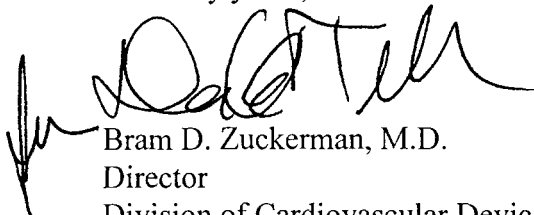
Page 2 – Ms. Jennifer Reich

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K030230DEVICE NAME: **AViTA BPM1 Series Wrist Type Blood Pressure Meter**
AViTA Corp.

INDICATIONS FOR USE:

The device is noninvasive and provide systolic, diastolic blood pressure and pulse rate (heart rate) measurements by using an inflating cuff which is wrapped around the wrist. All values can be read out in one LCD panel. The device is indicated for use by people over 15 years old in home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use *[Signature]* Over-The-Counter X
(Per 21 CFR 801.109) (Division Sign-Off) (Optional Format)
Division of Cardiovascular Devices

510(k) Number K030230